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PTO/SB (12-97)
OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Modified Form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)	Application Number	10/665,079
	Filing Date	09/16/03
	First Named Inventor	Bacopoulos
	Group Art Unit	1614
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	24852-501 CIP5

U.S. PATENT DOCUMENTS

Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date
	A1*	5,055,608	10/08/91	Marks et al.	560	169	06/30/89
	A2*	5,175,191	12/29/92	Marks et al.	514	575	05/14/90
	A3*	5,369,108	11/29/94	Breslow et al.	514	266	10/04/91
	A4*	5,608,108	03/04/97	Marks et al.	562	621	04/17/95
	A5*	5,700,811	12/23/97	Breslow et al.	514	314	05/19/94
	A6*	5,773,474	06/30/98	Breslow et al.	514	616	06/07/95
	A7*	5,932,616	08/13/99	Breslow et al.	514	532	04/04/94
	A8*	6,087,367	06/11/00	Breslow et al.	514	266	05/18/99
	A9*	6,511,990	01/28/03	Breslow et al.	514	314	08/24/00

FOREIGN PATENT DOCUMENTS

Exam Initials	Cite No.	Foreign Patent Document Office Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes No
	B1*	WO 98/40080	Beacon Laboratories, L.L.C.	September 17, 1998	X
	B2*	WO 00/21979	Fujisawa Pharmaceutical Co., LTD	April 20, 2000	X
	B3*	WO 00/71703	Methylgene, Inc.	November 30, 2000	X
	B4*	WO 01/18171	Sloan-Kettering Institute for Cancer Research & The Trustees of Columbia University in the City of New York	March 15, 2001	X
	B5*	WO 01/38322	Methylgene, Inc.	May 31, 2001	X
	B6*	WO 01/70675	Methylgene, Inc.	September 27, 2001	X
	B7*	WO 02/22577	Novartis-Erfindungen Verwaltungsgesellschaft M.B.H.	March 21, 2002	X
	B8*	WO 02/30879	Prolifix Limited	April 18, 2002	X
	B9*	WO 02/46144	F. Hoffmann-La Roche AG	June 13, 2002	X

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
	C1*	Andrews et al. (2000). <i>Intl. J. Parasitol.</i> 30: 761-768.
	C2*	Archer et al. (1998). <i>Proc. Natl. Acad. Sci. USA</i> 95: 6791-6796.
	C3*	Bhalla et al. (2002). "Co-treatment With The Histone Deacetylase Inhibitor Suberoylanilide Hydroxamic Acid (SAHA) Enhances the Cytotoxic Effects of Gleevec and Arsenic Trioxide (AT) Against Bcr-Abl Positive Human Leukemia Cells." <i>American Society of Hematology, 44th Meeting of the American Society of Hematology, Abstract 4611.</i>
	C4*	Butler et al. (2000). <i>Cancer Res.</i> 60: 5165-5170.
	C5*	Butler et al. (2001). <i>Clinical Cancer Res.</i> 7: 962-970.
	C6*	Butler et al. (2002). <i>Proc. Natl. Acad. Sci. USA</i> 99: 11700-11705.
	C7*	Coffey et al. (2000). <i>Medical and Pediatric Oncology</i> 35: 577-581.

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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
	C8*	Coffey et al. (2001). <i>Cancer Res.</i> <u>61</u> : 3591-3594.
	C9*	Cohen et al. (1999). <i>Anticancer Res.</i> <u>19</u> : 4999-5006.
	C10*	Cohen et al. (2002). <i>Anticancer Res.</i> <u>22</u> : 1497-1504.
	C11*	Curtin (2002). <i>Exp. Opin. Ther. Patents</i> <u>12</u> : 1375-1384.
	C12*	Dressel (2000). <i>Anticancer Res.</i> <u>20</u> : 1017-1022.
	C13*	Fei et al. (2002). "Co-treatment With the Histone Deacetylase Inhibitor Suberoylanilide Hydroxamic Acid (SAHA) Enhances Apo-2L/TRAIL-induced Death Inducing Signaling Complex and Apoptosis of Human Acute Lymphoid Leukemia Cells." <i>American Society of Hematology</i> , 44 th Meeting of the American Society of Hematology Abstract No. 4602.
	C14*	Feinman et al. (2002). "The Histone Deacetylase Inhibitor, Suberoylanilide Hydroxamic Acid, Induces Apoptosis of Multiple Myeloma Cells." <i>American Society of Hematology</i> , 44 th Meeting of the American Society of Hematology, Abstract No. 3195.
	C15*	Finnin et al. (1999). <i>Nature</i> <u>401</u> : 188-193.
	C16*	Furamai et al. (2001). <i>Proc. Natl. Sci. USA</i> <u>98</u> : 87-92.
	C17*	Grunstein (1997). <i>Nature</i> <u>389</u> : 349-352.
	C18*	He et al. (2001). <i>J. Clin. Investigation</i> <u>108</u> : 1321-1330.
	C19*	Hockly et al. (2003). <i>Proc. Natl. Acad. Sci. USA</i> <u>100</u> : 2041-2046.
	C20*	Kelly et al. (2001). "Suberoylanilide Hydroxamic Acid (SAHA), a Histone Deacetylase Inhibitor: Biologic Activity Without Toxicity." <i>American Society of Clinical Oncology</i> , Abstract No. 344.
	C21*	Kelly et al. (2002). "Histone deacetylase inhibitor, suberoylanilide hydroxamic acid (SAHA), orally administered has good bioavailability and biologic activity." <i>American Society of Clinical Oncology</i> , 38 th Annual Meeting of the American Society of Clinical Oncology, November 7-10, 2002, Abstract No. 1831.
	C22*	Kelly et al. (2002). "A phase I clinical trial of an oral formulation of the histone deacetylase inhibitor suberoylanilide hydroxamic acid (SAHA)." <i>European J. Cancer</i> <u>38</u> (Suppl. 7): 88, Abstract No. 286.
	C23*	Kim et al. (1999). <i>Oncogene</i> <u>18</u> : 2461-2470.
	C24*	Kohge et al. (1998). <i>Biochem. Pharmacol.</i> <u>56</u> : 1359-1364.
	C25*	Komatsu et al. (2001). <i>Cancer Res.</i> <u>61</u> : 4459-4466.
	C26*	Kouraklis and Theocharis (2002). <i>Curr. Med. Chem. Anti-Cancer Agents</i> <u>2</u> : 477-484.
	C27*	Lee et al. (2001). <i>Cancer Res.</i> <u>61</u> : 931-934.
	C28*	Lin et al. (1998). <i>Nature</i> <u>391</u> : 811-814.
	C29*	Mai et al. (2001). <i>OPPI Briefs</i> <u>33</u> : 391-394.
	C30*	Marks et al. (2000). <i>J. of the Natl. Cancer Institute</i> <u>92</u> : 1210-1215.
	C31*	Marks et al. (2001). <i>Clinical Cancer Res.</i> <u>7</u> : 759-760.
	C32*	Marks et al. (2001). <i>Curr. Opin. In Oncology</i> <u>13</u> : 477-483.
	C33*	Marks et al. (2001). <i>Nature Reviews</i> <u>1</u> : 194-202.
	C34*	Miller et al. (2003). <i>J Med Chem.</i> <u>46</u> : 5097-5116.
	C35*	Munster et al. (2001). <i>Cancer Res.</i> <u>61</u> : 8492-8497.
	C36*	O'Connor et al. (2002). "Clinical experience of the histone deacetylase inhibitor suberoylanilide hydroxamic acid (SAHA) in heavily pre-treated patients with aggressive non-hodgkin's lymphoma (NHL) and hodgkin's disease (HD)." <i>American Society of Clinical Oncology</i> , December 6-10, 2002, Abstract No. 4742.
	C37*	Qui et al. (2000). <i>Mol. Biol. Cell</i> <u>11</u> : 2069-2083.
	C38*	Richon et al. (1996). <i>Proc. Natl. Acad. Sci. USA</i> <u>93</u> : 5705-5708.
	C39*	Richon et al. (1998). <i>Proc. Natl. Acad. Sci. USA</i> <u>95</u> : 3003-3007.
	C40*	Richon et al. (2000). <i>Proc. Natl. Acad. Sci. USA</i> <u>97</u> : 10014-10019.
	C41*	Richon and O'Brien (2002). <i>Clinical Cancer Res.</i> <u>8</u> : 662-664.
	C42*	Saito et al. (1999). <i>Proc. Natl. Acad. Sci. USA</i> <u>96</u> : 4592-4597.
	C43*	Sgouros et al. (2002). "Synergistic Interaction of Suberoylanilide Hydroxamic Acid (SAHA) and

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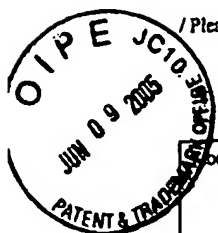
OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
		Radiation in Human Prostate Tumor Spheroids." <i>American Society of Clinical Oncology</i> , Abstract No. 105.
	C44*	Stowell et al. (1995). <i>J. Med. Chem.</i> 38: 1411-1413.
	C45*	Stu et al. (2000). <i>Cancer Res.</i> 60: 3137-3142.
	C46*	Suzuki et al. (1999). <i>J. Med. Chem.</i> 42: 3001-3003.
	C47*	Van Lint et al. (1996). <i>Gene Expression</i> 5: 245-253.
	C48*	Vrana et al. (1999). <i>Oncogene</i> 18: 7016-7025.
	C49*	Webb et al. (1999). <i>J. Biol. Chem.</i> 274: 14280-14287.
	C50*	Yoshida et al. (1990). <i>J. Biol. Chem.</i> 265: 17174-17179.
	C51*	Yoshida et al. (1995). <i>BioEssays</i> 17: 423-430.
	C52*	Zhou et al. (1999). <i>Gene</i> 233: 13-19.
	C53*	Zhou et al. (2000). <i>Proc. Natl. Acad. Sci. USA</i> 97: 1056-1061.
	C54*	Zhou et al. (2000). <i>Proc. Natl. Acad. Sci. USA</i> 97: 14329-14333.
	C55*	Zhou et al. (2001). <i>Proc. Natl. Acad. Sci. USA</i> 98: 10572-10577.

*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. 10/379,149, filed March 4, 2003, and relied upon for an earlier filing date under 35 U.S.C. §120 (continuation, continuation-in-part, and divisional applications).

Examiner Signature		Date Considered	
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Modified Form 1449/PTO SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)	Application Number	10/665,079
	Filing Date	09/16/03
	First Named Inventor	Bacopoulos
	Group Art Unit	1614
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	24852-501 CIP5

U.S. PATENT DOCUMENTS							
Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date
CM	A13	6,231,880	05/15/2001	Perrine	424	423	05/29/1998
	A14	2004/0002506	12/30/2004	Breslow et al.	514	310	04/01/2004
	A15	2004/0087631	05/06/2004	Bacopoulos et al.	514	352	08/26/2003
	A16	2004/0122101	06/24/2004	Miller et al.	514	575	06/19/2003
	A17	2004/0127522	07/01/2004	Chiao et al.	514	352	07/09/2003
	A18	2004/0266818	01/01/2004	Breslow et al.	514	263.4	10/25/2002
	A19	2004/0072735	04/15/2004	Richon et al.	514	9	03/04/2003
	A20	2004/0132825	07/08/2004	Bacopoulos et	514	575	10/24/2003

FOREIGN PATENT DOCUMENTS					
Exam Initials	Cite No.	Foreign Patent Document Office Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes No
CM	B10	WO 01/16106	Schering Aktiengesellschaft	03/08/2001	X

NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
CM	C60	Adams and Elliott (2000). <i>Oncogene</i> <u>19</u> : 6687-6692.
	C61	Bates et al. (1999). <i>Proc. American Society of Clinical Oncology</i> <u>18</u> : 180a, Abstract No. 693
	C62	Foster et al. (1997). <i>Invest. New Drugs</i> <u>15</u> : 187-194.
	C63	Gojo et al. (2002). <i>Blood</i> <u>100</u> : Abstract No. 2198.
	C64	Gore and Carducci (2000). <i>Exp. Opin. Invest. Drugs</i> <u>9</u> : 2923-2934.
	C65	Huang and Pardee (2000). <i>Molecular Medicine</i> <u>6</u> : 849-866.
	C66	Johnstone, R. (2002). <i>Nature Reviews Drug Discovery</i> <u>1</u> : 287-299.
	C67	Kelly et al. (2002). <i>Exp. Opin. Invest. Drugs</i> <u>11</u> : 1695-1713.
	C68	Kelly et al. (2002). <i>Proc. American Society of Clinical Oncology</i> <u>21</u> : 6b, Abstract No. 1831.
	C69	Kelly et al. (2001). <i>Proc. American Society of Clinical Oncology</i> <u>20</u> : 87a, Abstract No. 344.
	C70	Kosugi et al. (2001). <i>Jpn. J. Cancer Res.</i> <u>92</u> : 529-536.
	C71	Marshall et al. (2002). <i>J. Exp. Therapeutics and Oncology</i> <u>2</u> : 325-332.

NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
cm	C72	Piekarz et al. (2001). <i>Blood</i> 98: 2865-2868.
	C73	Prakash et al. (2001). <i>Invest. New Drugs</i> 19: 1-11.
	C74	Rha et al. (1993). <i>J. Korean Med. Sci.</i> 8:251-256.
	C75	Rifkind et al. (2002). 224 th ACS National Meeting, Boston, MA, Abstract No. 226.
	C76	Sandor et al. (2002). <i>Clinical Cancer Research</i> 8: 718-728.
	C77	Secrist et al. (2003). <i>Curr. Opin. Invest. Drugs</i> 4:1422-1427.
	C78	Summerhayes, M. (2001). <i>J. Oncol. Pharm. Prac.</i> 7: 107-125.
	C79	Vigushin, D. (2002). <i>Current Opin. Invest. Drugs</i> 3: 1396-1402.
	C80	Warrell et al. (1998). <i>J. Natl. Cancer Institute</i> 90: 1621-1625.

*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. _____, filed _____, and relied upon for an earlier filing date under 35 U.S.C. §120 (continuation, continuation-in-part, and divisional applications).

Examiner Signature	cm	Date Considered	10-2-05
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CM	A10	6,451,334	09/17/02	Perrine			04/30/01
	A11	2003/0161830	08/28/03	Jackson et al.			06/14/02
	A12	2004/0127523	07/01/04	Bacopoulos et al.			09/16/03

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NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
CM	C56	International Search Report for PCT/US03/06451, mailed October 27, 2003
	C57	International Preliminary Examination Report for PCT/US03/06451, mailed August 3, 2004
	C58	International Search Report for PCT/US04/27943, mailed March 7, 2005
	C59	Wu et al. (2001). "Negative Regulation of bcl-2 Expression by p53 in Hematopoietic Cells." <i>Oncogene</i> 20(2): 240-251, Abstract, Database CAPLUS on STN, Acc. No. DN134:293668.

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cm	A21	RE38,506 E	04/20/04	Breslow, et al.	514	316	10/04/1991
J	A22	2003/0082666	05/01/03	Kammer, et al.	435	18	07/02/2002
J	A23	2003/0235588	12/25/03	Richon, et al.	424	146.1	02/14/2003

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cm	C81	O'Connor et al. (2001). <i>Journal of the American Society of Hematology</i> 611a, Abstract No. 2562.
cm	C82	Kelly, et al. (2003). <i>Clinical Cancer Research</i> 9:3578-3588.

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